Claims

What is claimed is:

1. A therapeutic composition comprising at least one isolated peptide having a defined sequence of amino acid residues, said composition being capable of down regulating an antigen specific immune response in a population of humans subject to said antigen specific immune response, when administered in non-immunogenic form.

2. The composition of claim 1 wherein said at least one peptide is derived from a protein antigen, and said antigen specific immune response is directed against said antigen.

3. The composition of claim 1 wherein said at least one peptide is purified to at least 95% purity.

4. A therapeutic composition comprising at least one isolated and purified peptide, said at least one peptide having a defined length, a defined sequence of amino acid residues, and comprises at least one T cell epitope of a protein antigen, said composition being capable of down regulating an antigen specific immune response to said protein antigen in a population of humans subject to said antigen specific immune response, when administered in non-immunogenic form.

5. The composition of claim 1 or 4 wherein said at least one peptide is of a defined length not to exceed fifty amino acid residues.

6. The composition of claim 4 wherein said at least one peptide is at least about 12 amino acid residues in length and no more than about 40 amino acid residues in length.

7. The composition of claim 4 wherein said antigen is a protein allergen.

8. The composition of claim 7 wherein said protein allergen selected from the group consisting of: a protein allergen of the genus *Dermatophagoides*; a protein allergen of the genus *Felis*; a protein allergen of the genus *Ambrosia*; a protein allergen of the genus *Lolium*; a protein allergen of the genus *Cryptomeria*; a protein allergen of the genus *Alternaria*; a protein allergen of the genus *Alder*; a protein allergen of the genus *Betula*; a protein allergen of the genus *Quercus*; a protein allergen of the genus *Olea*; a protein allergen of the genus *Artemisia*; a protein allergen of the genus *Plantago*; a protein allergen of

the genus *Parietaria*; a protein allergen of the genus *Canine*; a protein allergen of the genus *Blattella*; a protein allergen of the genus *Apis*; a protein allergen of the genus *Cupressus*; a protein allergen of the genus *Juniperus*; a protein allergen of the genus *Thuya*; a protein allergen of the genus *Chamaecyparis*; a protein allergen of the genus *Periplaneta*; a protein allergen of the genus *Agropyron*; a protein allergen of the genus *Secale*; a protein allergen of the genus *Triticum*; a protein allergen of the genus *Dactylis*; a protein allergen of the genus *Festuca*; a protein allergen of the genus *Poa*; a protein allergen of the genus *Avena*; a protein allergen of the genus *Holcus*; a protein allergen of the genus *Anthoxanthum*; a protein allergen of the genus *Arrhenatherum*; a protein allergen of the genus *Agrostis*; a protein allergen of the genus *Phleum*; a protein allergen of the genus *Phalaris*; a protein allergen of the genus *Paspalum*; and a protein allergen of the genus *Sorghum halepensis*.

9. The composition of claim 8, wherein the protein allergen is selected from the group consisting of: *Der p* I; *Der p* II; *Der p* III; *Der p* VII; *Der f* I; *Der f* II; *Der f* III; *Der f* VII; *Fel d* I; *Amb a* I.1; *Amb a* I.2; *Amb a* I.3; *Amb a* I.4; *Amb a* II; *Lol p* I; *Lol p* II; *Lol p* III; *Lol p* IV; *Lol p IX* (*Lol p* V or *Lol p* Ib); *Cry j* I; *Cry j* II; *Can f* I; *Can f* II; *Jun s* I; *Jun v* I; *Dac g* I; *Poa p* I; *Phl p* I; and *Sor h* I.

10. The composition of claim 4 wherein said protein antigen is an autoantigen.

11. The composition of claim 10 wherein the autoantigen is selected from the group consisting of: insulin; myelin basic protein; myelinoligodendrocyte protein, rh factor; acetylcholine receptors; thyroid cell receptors; basement membrane proteins; thyroid proteins; ICA-69 (PM-1); glutamic acid decarboxylase (64K and 65 K); Proteolipid protein (PLP); myelin associated glycoprotein (MAG); collagen (Type II); Heat Shock Protein; and carboxypeptidase H.

12. A composition of claim 4 wherein said at least one peptide is not derived from said protein antigen, said peptide being capable of mimicking a T cell epitope of said antigen.

13. A composition of claim 4 wherein said at least one peptide is a cryptic peptide of said protein antigen.

14. The composition of claim 4 wherein said at least one peptide has a mean T cell stimulation index of at least about 3.5 determined in an *in vitro* T cell proliferation assay with T cells obtained from a population of humans sensitive to said allergen.

15. The composition of claim 14 wherein said at least one peptide has a positivity index of at least 150 as determined in an *in vitro* T cell proliferation assay with T cells obtained from a population of humans sensitive to said allergen.

16. The composition of claim 4 wherein said at least one peptide comprises a sufficient percentage of T cell epitopes of said protein antigen, such that, upon administration of said composition, the development or progression of the disease symptoms caused by the antigen are reduced.

17. The composition of claim 16 wherein said at least one peptide comprises at least 20% of the T cell epitopes of said protein allergen.

18. The composition of claim 7 wherein said at least one peptide does not bind IgE or binds IgE to substantially lesser extent than said protein naturally occurring allergen binds IgE.

19. The composition of claim 4 wherein said at least one peptide has been purified to homogeneity.

20. The composition of claim 19 wherein said at least one peptide has been purified to at least about 95% purity.

21. The composition of claim 4 wherein said at least one peptide is produced in accordance with a method selected from the group consisting of: chemical synthesis, recombinant DNA techniques, chemical cleavage of a purified whole protein, and enzymatic cleavage of a purified whole protein.

22. A therapeutic composition of claim 4 further comprising at least one pharmaceutically acceptable carrier.

23. A therapeutic composition of claim 22 wherein said pharmaceutically acceptable carrier comprises is selected from the group consisting of sterile water, sodium phosphate, mannitol, sorbitol, sodium chloride, and any combination thereof.

24. The composition of claim 1, 4, 16 or 22 wherein said composition is soluble in an aqueous solution at a physiologically acceptable pH.

25. The composition of claim 1, 4, 16, or 22 wherein said at least one peptide comprises a sufficient percentage of T cell epitopes of said protein antigen, such that, upon administration of said composition, the development or progression of the disease symptoms caused by the antigen are eliminated.

26. The composition of claim 4 wherein said at least one peptide is present in a dosage range of about 1 μg - 3.0 mg of peptide per dosage unit.

27. The composition of claim 26 wherein said at least one peptide is present in a dosage range of about 20 μg - 1.5 mg of peptide per dosage unit.

28. The composition of claim 27 wherein said at least one peptide is present in a dosage range of about 50 μg - 750 μof peptide per dosage unit.

29. The composition of claim 1, 4, 16, or 22 comprising at least two peptides.

30. A method of treating humans sensitive to an antigen comprising administering at least one therapeutic composition of claim 4.

31. A method of treating humans sensitive to an antigen comprising administering a therapeutic composition comprising at least two isolated and purified peptides, each of said peptides having a defined length, a defined sequence of amino acid residues, and comprising at least one T cell epitope of a protein antigen, said composition being capable of down regulating an antigen specific immune response to said protein antigen in a population of humans subject to said antigen specific immune response, when administered in non-immunogenic form, wherein said composition is soluble in an aqueous solution and stable at a physiologically acceptable pH.

32. A method of treating humans sensitive to an antigen comprising administering simultaneously or sequentially at least two compositions of claim 4.

33. A method of treating humans sensitive to an antigen comprising administering simultaneously or sequentially at least two compositions of claim 31.

34. The method of claim 30 wherein said administering comprises oral administration of said composition.

35. The method of claim 30 wherein said administering comprises subcutaneous injection of said composition.

36. The method of claim 35 further comprising administering an initial treatment of composition, said initial treatment comprising subsequent injections of composition once a week for at least about 3 weeks and no more than about 6 weeks.

37. The method of claim 36 further comprising administering a booster injection of said composition at intervals of at least about three months after said initial treatment.

38. The method of claim 36 wherein said initial treatment comprises increasing the dosage with each subsequent injection.

39. The method of claim 30 wherein said antigen is a protein allergen or an autoantigen.

40. The method of claim 36 wherein said initial treatment comprises decreasing the dosage with each subsequent injection.

41. The method of claim 30 wherein said administering comprises sublingual administration of said composition.

42. The method of claim 30 wherein said administering comprises intravenous injection of said composition.

43. A method of treating humans sensitive to an antigen comprising administering at least one therapeutic composition of claim 1, 16, 22, or 26.